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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/837,129 | 04/18/2001 | Misaki Ishida | 3274-010528 | 7371 |

7590

12/03/2002

Kent E. Baldauf
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818

EXAMINER

WILLIS, MICHAEL A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,129

Applicant(s)

ISHIDA ET AL.

Examiner

Michael A. Willis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment of 4 November 2002 is entered. Claims 4-7 are cancelled. Claim 1 is amended. Claims 15-18 are added. Claims 1-3 and 8-18 are pending. Claims 8-14 are withdrawn from consideration as being directed to a non-elected invention, as indicated in a previous Office Action. Any previous rejections that are not restated in this Office Action are hereby withdrawn. Applicant's arguments will be addressed as they apply to the new grounds of rejection. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Request for Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

The following new grounds of rejection are made:

Claim Rejections - 35 USC § 112

Claims 1-3 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for being vague due to the term "lower alcohol". It is noted that the specification gives examples of lower alcohol such as ethanol and isopropyl alcohol (see specification, page 13, lines 6-7). However, the metes and bounds of "lower alcohol" are unclear. For example, it is unclear whether or not hexanol or octanol qualify as lower alcohols.

Claims 1, 2, 3, 15, and 17 are rejected for being confusing due to the term "polymethoxyflavone". As used in the claims, the term appears to signify one or more polymethoxyflavones rather than a single compound. The rejection can be modified by substituting "one or more polymethoxyflavones" (or similar language as chosen by applicant) for the term "polymethoxyflavone".

Any remaining claims are rejected for depending from an indefinite base claim.

Claim Rejections - 35 USC § 103

Claims 1-3 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dornoff et al (US Pat. 5,916,576) in view of Swift (US Pat. 3,598,841) and Hadas et al (GB 2 259 014 A).

The instant claims are directed to compositions comprising polymethoxyflavones represented by formula (I) in combination with a whitening agent and a cosmetic vehicle consisting essentially of water and additional components. With respect to claims 15-18, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a

different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP § 2113, which states that once a product appearing to be substantially identical is found and a rejection made, the burden shifts to the applicant to show an unobvious difference.

Dornoff teaches compositions comprising an orange extract for the preparation of compositions with anti-radical activity (see abstract). Dornoff clearly teaches that the orange extract is the active ingredient (see col. 2, lines 65-67). While the compositions are described by Dornoff as being substantially free of ascorbic acid or its derivatives, this amount is actually defined as being no more than 1% by weight ascorbic acid or its derivatives (see col. 3, lines 1-5). Therefore, the amount of ascorbic acid or its derivatives as taught by Dornoff overlaps with the instant claims. Dornoff teaches that the orange extract is preferably obtained from orange peel (see col. 3, lines 10-11). The amount of extract used ranges from 0.01 to about 50% (see col. 3, lines 25-30). Cosmetic ingredients such as alcohols, fats and oils are taught (see col. 3, lines 35-40). Additionally, Dornoff teaches the desirability of incorporating the orange extract in a skin-whitening composition where the orange extract augments known tyrosinase inhibitors and provides enhanced skin whitening properties (see col. 3, lines 43-52). The reference lacks disclosure of the compounds inherently contained within the orange extract, as well as specific tyrosinase inhibitors.

Swift teaches that nobiletin (5,6,7,8,3',4'-hexamethoxyflavone) is found in the peel of oranges. Swift teaches that juice squeezed from orange peel contains about 0.1 grams per liter and is associated with a number of other closely related compounds (see

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col. 1, lines 30-35). Swift therefore establishes that nobiletin and related compounds are inherently present in the extracts taught by Dornoff in amounts overlapping with the claimed weight percentage. Furthermore, even in the absence of such evidence, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Hadas teaches the use of flavonoid-containing compositions for skin-whitening methods (see abstract). Hadas teaches that an advantageous ingredient in the compositions is kojic acid (see page 3, lines 7-10). Hadas teaches that kojic acid is used in order to inhibit tyrosinase activity (see page 3, lines 7-1). Hadas further teaches that kojic acid enhances the whitening effect of flavonoids and ascorbic acid and its derivatives through a synergistic effect (see page 19, lines 17-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Dornoff by the inclusion of kojic acid as a species of tyrosinase inhibitor in order to benefit from its synergistic effect in whitening skin. The motivation for the addition of kojic acid comes from the teaching of Hadas that kojic acid provides an enhancement of the whitening effect of flavonoids and ascorbic acid.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on alt. Mondays and Tuesday to Friday (9am-6:30pm).

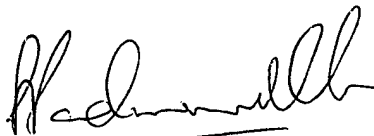
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis
Examiner
Art Unit 1617

maw
November 26, 2002



SREENI PADMANABHAN
PRIMARY EXAMINER

